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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/440,384 11/15/99 KINGSFORD

H 05918-153001

EXAMINER
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IM52/0523

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BOSTON MA 02110-2804

PATTERSON, M	
ART UNIT	PAPER NUMBER

1772  
DATE MAILED:

05/23/01

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/440,384

Applicant(s)

KINGSFORD, HOWARD A.

Examiner

Marc A Patterson

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 November 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
  2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
  3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to Claim 1, the terms 'being configured,' 'at least,' and 'at least many,' are indefinite. For purposes of examination, 'being configured' will be assumed to mean 'oriented'. Claim 10 appears to be missing a word. With regard to Claim 17, the term 'groove' is indefinite; for purposes of examination it will be assumed to mean any depressions which are defined by elevated peaks on a surface.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 1 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609) and Coates (U.S. Patent No. 4,219,019).

With regard to Claim 1, Reed et al. disclose an array (plurality) of surfaces having a pointed shape (column 3, lines 16 – 22; column 60 – 66) formed of plastic (column 3, lines 40 – 42) which is used to pierce (penetrate) skin (column 4, lines 28 – 32); it is therefore a skin

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attachment member of plastic resin, and is configured to penetrate into the epidermal skin layer; the skin attachment has a sheet form backing from which the penetrating elements extend integrally (base; column 7, lines 26 – 27), and is used as a bandage (column 5, lines 21 – 26); the skin penetrating elements include a retention barb extending from an outer surface of the skin penetrating element. Reed et al. fail to disclose a skin penetrating element which is sized to limit painful contact with the nerves below the epidermal skin layer, and barbs which are configured to cooperate to resist removal of the skin attachment member from skin. The size and configuration of the penetrating elements, however, would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

With respect to Claim 4, the surfaces of the skin penetrating elements have pointed shapes (column 3, lines 16 – 22; column 60 – 66), and therefore, pointed tips.

With respect to Claim 10, each skin penetrating element includes two barbs (column 3, lines 60 – 66, Figure 6).

With respect to Claim 13, Reed et al. fail to disclose a skin attachment member comprising nylon. Fye teaches the use of nylon in the making of bandages, for the purpose of making bandages which are light – weight and hand – washable (column 2, lines 34 – 39). It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for nylon in Reed et al. in order to make bandages which are hand – washable as taught by Fye.

With respect to Claim 14 and 15, Reed et al. fail to disclose a skin attachment member comprising polyethylene terephthalate (which is a polyester). Coates teaches the use of

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polyethylene terephthalate in the making of bandages, for the purpose of making bandages which possesses bulk and conformability. It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for polyethylene terephthalate in Reed et al. in order to make bandages which possesses bulk and conformability as taught by Coates.

With regard to Claim 16, the scope of the claim falls within the limitation of Reed et al. as discussed above. The process of making the skin attachment member (product – by – process) is given little patentable weight. Applicant would need to demonstrate, by verified showing, the unexpected advantages accruing from the methods of coating application as claimed.

With regard to Claim 17, the skin penetrating elements have pointed shapes, and therefore define depressions on the surface.

With regard to Claims 2, 3, 5 – 9, 11 – 12 and 18, Reed et al. and Fye and Coates fail to disclose a skin penetrating element comprising a cone – shaped body, and a cone – shaped body having a diameter of about 0.003”, and a skin penetrating element having a diameter of 0.003”, and a skin penetrating element having a length of 0.012” and a backing having a thickness of 0.003 to 0.008”, and a retention barb which is 0.008” to 0.0095” from the backing, and a retention barb with a length of 0.0001”, and a retention barb which tapers from a thickness of 0.0001” to a point at an angle of 72 degrees, and a skin attachment member having a density of 400 skin penetrating elements in a 0.1 in<sup>2</sup> area and the elements are spaced apart from each other a distance of 0.003, and the elements are perpendicular to the backing. However, the shape of the skin penetrating elements (including diameter), the length of the elements, the thickness of the backing, the location of the retention barb, the length of the retention barb, the angle and

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thickness from which the retention barb tapers, the density and spacing of skin penetrating elements, and the angle of the elements relative to the backing would be readily determined through routine experimentation by one having ordinary skill in the art depending on the desired end result. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

### ***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Patterson, whose telephone number is (703) 305-3537. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by phone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (703) 308-2364. FAX communications should be sent to (703) 305-3599. FAXs received after 4 P.M. will not be processed until the following business day.

M.A.P.

*M.A.P.*

  
HAROLD PYON  
SUPERVISORY PATENT EXAMINER  
1772

5/21/01